This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Eftrenonacog alfa

(genetical recombination)

June 5, 2018

Non-proprietary name

Eftrenonacog alfa (genetical recombination)

Branded name (Marketing authorization holder)

Alprolix Intravenous 250, 500, 1000, 2000, 3000, 4000 (Vioverative Inc.)

Indications

Inhibition of bleeding tendency in patients with blood coagulation factor IX deficiency

Summary of revision

A Clinically Significant Adverse Reactions section should be newly added and “Shock, anaphylaxis” should be listed within.

Investigation results and background of revision items

Cases of shock or anaphylaxis have been reported in patients treated with eftrenonacog alfa (genetical recombination) in Japan and overseas. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

One case involving shock or anaphylaxis has been reported to date (a causal relationship with the product could not be ruled out for this case.)

No patient mortalities have been reported to date.

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